

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK**

FEDERAL TRADE COMMISSION;
STATE OF NEW YORK; STATE OF
CALIFORNIA; STATE OF ILLINOIS;
STATE OF NORTH CAROLINA; STATE
OF OHIO; COMMONWEALTH OF
PENNSYLVANIA; and
COMMONWEALTH OF VIRGINIA,

Plaintiffs,

v.

VYERA PHARMACEUTICALS, LLC;
PHOENIXUS AG; MARTIN SHKRELI,
individually, as an owner and former officer
of Vyera Pharmaceuticals, LLC and
Phoenixus AG (formerly known as Turing
Pharmaceuticals, LLC and Turing
Pharmaceuticals AG); and KEVIN
MULLEADY, individually, as an owner and
director of Phoenixus AG and a former
executive of Vyera Pharmaceuticals, LLC

Defendants.

Case No. 1:20-cv-00706-DLC

**REPLY BRIEF IN FURTHER SUPPORT OF DEFENDANT MARTIN SHKRELI'S
MOTION TO STAY ORDER FOR PERMANENT INJUNCTION PENDING APPEAL**

I. INTRODUCTION

Plaintiffs' Opposition (ECF 896) to Defendant Martin Shkreli's Motion to Stay Order for Permanent Injunction Pending Appeal (ECF 879) fails to rebut Mr. Shkreli's arguments as to why he is entitled to a stay of the permanent injunction that the Court ordered. Plaintiffs fail to rebut Mr. Shkreli's argument that he is likely to succeed on the merits of his appeal, for several reasons:

First, plaintiffs fail to offer any justification for such a far-reaching and punitive sanction as a lifetime ban from the pharmaceutical industry. Nor do they explain why a more narrowly-tailored injunction, which is tied to the conduct that the Court held to be illegal, cannot be enforced.

Second, plaintiffs do not rebut Mr. Shkreli's argument that the Court erred in holding that plaintiffs met their burden to prove that Vyera's supply and distribution agreements caused anticompetitive effects. Plaintiffs concede that the Court did not use the standard for evaluating the legality of exclusive distribution agreements—"substantial foreclosure of competition in the relevant market."—that courts have used for more than 60 years. And plaintiffs' arguments for why the standard the Court *did* apply is appropriate are unavailing. In addition, plaintiffs offer no record evidence to support the Court's conclusion that plaintiffs met their burden to prove causation, a necessary element of any antitrust claim.

Third, plaintiffs fail to rebut Mr. Shkreli's argument that the Court erred in imposing joint and several liability under the standards of the *Liu* case. The record contains neither evidence that Mr. Shkreli personally profited from any of Vyera's agreements, nor evidence that he participated in "concerted wrongdoing" with respect to the challenged agreements.

Fourth, plaintiffs fail to rebut Mr. Shkreli's argument that they have failed to prove that the relevant product market is FDA-approved pyrimethamine products. The record evidence shows that the product market contains other treatments that are not FDA-approved, including TMP-SMX.

For all these reasons, in addition to those in Mr. Shkreli's opening brief, the Court should stay the injunction pending appeal.

II. ARGUMENT

A. Plaintiffs Fail to Rebut That the Court Abused its Discretion in Issuing a Permanent Injunction That is Not Narrowly Tailored to the Conduct at Issue.

Plaintiffs are unable to offer any justification for the Court's far-reaching and punitive permanent injunction – a lifetime, industry-wide pharmaceutical ban.

They do not contest that the injunction restrains more than the alleged misconduct at issue. However, they argue that the injunction does not restrain “purely *legal* conduct.” Opp. at p. 3 n.2 (emphasis in original). This is plainly not the case because the injunction bans Mr. Shkreli for life from *all* participation in the pharmaceutical industry. By definition, “all participation” includes purely *legal* activity, such as researching pharmaceutical drugs or developing advertisements for pharmaceuticals.

None of plaintiffs' other arguments in support of the enforceability of an industry-wide ban fares any better. For example, plaintiffs argue that a lifetime, industry-wide pharmaceutical ban is “narrowly tailored” because “Shkreli both regularly starts new businesses and controls businesses indirectly.” Plaintiffs' Opposition, at p. 3. Plaintiffs neither define “regularly” nor explain why a history of entrepreneurship – in a nation built upon it – can constitute a valid basis to bar a person from “participating” in an entire industry for life. Additionally, there is no record evidence to support this assertion, nor could there be for a defendant who has been incarcerated since 2017.

Equally unavailing is plaintiffs' assertion that an industry ban is appropriate because Mr. Shkreli allegedly operated “without any regard for those harmed by his conduct.” *Id.* at pp. 3-4.

Plaintiffs do not define “those harmed by his conduct.” And there is no record support for this bald assertion.

Plaintiffs argue that an industry-wide injunction is required because a “conduct-specific injunction” would be too difficult to monitor and enforce against “an individual like Shkreli.” *Id.* This argument fails for several reasons. First, there is no evidence that Mr. Shkreli has ever attempted to “evade detection” by this Court of his conduct, or to avoid “leaving a paper trail” (*id.* at 3). Thus, there is no basis for plaintiffs’ suggestion that he would disregard an order of this Court through surreptitious means. Second, plaintiffs do not explain how a conduct-specific injunction would be more difficult to monitor and enforce against Mr. Shkreli than against a company like Vyera. If the Court issued an injunction that was narrowly tailored to the specific conduct it held to be illegal, the regular reporting requirements in the injunction—the same ones that are applicable to Vyera—would suffice to ensure Mr. Shkreli’s compliance with the order. Thus, plaintiffs offer no grounds upon which the Second Circuit could conceivably uphold the industry-wide lifetime injunction entered in this case.

B. Plaintiffs Fail to Rebut That the Court Erred in Holding that Vyera’s Agreements Caused Anticompetitive Effects.

1. Plaintiffs Do Not Rebut That the Court Failed to Apply the Correct Legal Standard.

Plaintiffs’ Opposition also does not rebut Mr. Shkreli’s argument that the Court applied the wrong legal standard for competitive effects and ignored the correct standard – “substantial foreclosure of competition in the relevant market.” *Tampa Elec. Co. v. Nashville Coal Co.*, 365 U.S. 320, 328 (1961). Plaintiffs implicitly concede that the Court failed to apply the *Tampa Elec. Co.* standard by arguing that it is “not substantively different” from the Court’s citation and analysis of *New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638, 656 (2d Cir. 2015) (“*Actavis PLC*”). Plaintiffs’ Opposition, at p. 5. But in fact, the *Actavis PLC* standard is different

than that set forth in *Tampa Electric*, in that it does not require proof of “substantial foreclosure of competition.” Rather, it requires a showing that the conduct had the anticompetitive effect of “bar[ring] a substantial number of rivals or severely restrict[ing] the market’s ambit.” Plaintiffs’ Opposition, p. 5. Moreover, plaintiffs fail to rebut that the *Actavis PLC* holding does not apply to exclusive supply agreements, so the Court should not have applied it to the API supply agreements in this case. See *Tampa Elec. Co.*, 365 U.S. at 328; *Fresenius Kabi USA, LLC v. ParSterile Prods., LLC*, 841 F. App’x 399, 404 n.12 (3d Cir. 2021).

Even assuming *arguendo* that the Court did not err in applying the *Actavis PLC* standard to this case, the record evidence falls far short of meeting it. First, the Court did not analyze whether a “substantial number” of competitors was barred from entry, nor did the Court analyze whether the market’s ambit was “severely restricted.”¹ Second, in an industry consisting of hundreds of generic pharmaceutical companies, the Court found only that two generic companies were delayed in entering the generic pyrimethamine market as a result of Vyera’s agreements. This record clearly does not support a finding that a “substantial number of rivals” was barred from entering the generic pyrimethamine market. Accordingly, whether the Court’s conclusions are evaluated under *Tampa Elec. Co.* or *Actavis*, the Court erred in holding that plaintiffs had met their burden to prove anticompetitive effects.²

¹ The Court based its conclusion that plaintiffs had met their burden to prove anticompetitive effects from the exclusive supply agreements on its finding that those agreements “closed off access to the two most viable suppliers of pyrimethamine for years.” ECF 865, at pp. 111-12. Although it is unclear what precedent the Court was relying on in making viability of potential suppliers the touchstone, this analysis is inconsistent with the *Tampa Elec. Co.* standard. See *id.*, 365 U.S. at 328 (holding that the correct standard for evaluating an exclusive supply agreement is “substantial foreclosure of competition in the relevant market”).

² Plaintiffs argue that “Shkreli did not establish that any other API manufacturer was a viable source of pyrimethamine API during the relevant period.” *Id.* at 6, n. 4. Plaintiffs are here engaging in classic burden-shifting. It was plaintiffs’ burden to prove—not Mr. Shkreli’s burden to disprove—substantial anticompetitive effects resulting from the challenged agreements. This they failed to do.

2. **Plaintiffs Do Not Rebut That the Court Erred in Holding that Plaintiffs Had Met Their Burden to Prove Causation.**

In their complaint, plaintiffs’ central allegation is that “[a]s the result of Vyera’s agreements restricting the resale of Daraprim, exclusive API agreements, and data-blocking agreements, at least four potential generic competitors have been delayed or excluded from the market.” Am. Compl. at ¶ 185. Despite this allegation, made before plaintiffs had to support the allegation with evidence in court, plaintiffs now argue that the Court need not find that the challenged agreements caused an *actual* delay in generic entry. Instead, plaintiffs argue that all they are required to show is that the agreements “‘impede the ordinary give and take of the marketplace,’” or are “‘likely enough to disrupt the proper functioning of the price-setting mechanisms of the market.’” Plaintiffs’ Opposition, at pp. 6-7 (citing *Nat’l Soc’y of Prof’l Eng’rs v. United States*, 435 U.S. 679, 692 (1978) and *FTC v. Ind. Fed’n of Dentists*, 476 U.S. 447, 461-62 (1986)). Plaintiffs’ about-face is understandable in light of their failure to actually prove delayed entry. But they fail to explain how this new vague standard of anticompetitive effects—which notably the Court does *not* apply—is supported by the record evidence.³

In addition, plaintiffs also offer no record support, other than the Court’s Opinion, that Vyera’s distribution and supply agreements, and not “business mistakes by the generic companies,” Plaintiffs’ Opposition, at p. 6, were the cause in fact of the alleged delay in generic entry.⁴ See *Lavoho, LLC v. Apple, Inc.*, 232 F. Supp. 3d 513, 525 (S.D.N.Y. 2016) (Cote, J.), *aff’d*

³ Plaintiffs argue that the Court’s finding that there was “direct evidence of increased prices in the relevant market,” *id.* at 7, suffices to prove anticompetitive effects. But the price increase alone—which was put in place before most, if not all, of the challenged agreements were executed—cannot suffice to prove anticompetitive effects from the later agreements.

⁴ The only support in the record for delay in generic companies’ entering the market is the speculative testimony by Vyera’s self-interested generic competitors that they would have been able to enter the market sooner if not for Vyera’s distribution and supply agreements.

sub nom. Diesel eBooks, LLC v. Simon & Schuster, Inc., 869 F.3d 55 (2d Cir. 2017) (“[a] lack of causation in fact is fatal to the merits of any antitrust claim.”).

Plaintiffs’ failure to prove actual delay is underscored by the Opposition’s assertion that the Court accepted Plaintiffs’ “estimate” – not evidence or proof – of the length of the alleged delay.

Accordingly, Mr. Shkreli is likely to succeed on the merits because the Court erred in holding that plaintiffs had met their burden of proving that the agreements at issue caused anticompetitive effects through a delay in the entry of generic competition.

C. Plaintiffs Fail to Rebut that the Court Erred in Holding Mr. Shkreli Jointly and Severally Liable.

Plaintiffs’ Opposition misconstrues the holding in *Liu v. SEC*, 140 S. Ct. 1936, 1949 (2020). Plaintiffs argue that the *Liu* holding does not set forth specific factors, but instead is nothing more than a regurgitation of “well-established equitable principles.” Plaintiffs’ Opposition, at p. 8. This assertion is difficult to comprehend given the enormous amount of legal scholarship and articles surrounding the ground-breaking *Liu* case and how its factors impact plaintiffs’ ability to obtain joint-and-several equitable monetary relief. *See, e.g.*, Aiste Zalepuga, *Updating the Federal Agency Enforcement Playbook*, 96 Notre Dame L. Rev. 2083, 2100 (2021) (“*Liu*’s second limiting principle suggests the FTC will no longer be able to impugn multiple defendants using joint and several liability, marking the end of a common practice by the FTC.”); Samuel Wolff and Alina Veneziano, *In Lieu Of Liu? Disgorgement In Sec Enforcement Practice Following The National Defense Authorization Act*, 43 No. 3 Securities and Federal Corporate Law Report NL 1; Ro Reynolds, *Limits on SEC Aggression: Liu v. SEC*, Columbia Business Law Review Online, available at <https://journals.library.columbia.edu/index.php/CBLR/announcement/view/402>.

Importantly, the *Liu* Court stated that joint and several liability may be appropriate under *limited circumstances* involving “partners engaged in concerted wrongdoing.” *Id.* In determining whether appropriate “limited circumstances” warrant the imposition of joint and several liability, the Court focused heavily on whether defendants personally misappropriated funds and personally profited from the illegal conduct, whether the finances of defendants and the businesses were commingled, and whether defendants were merely passive recipients of the profits. *Id.*

A proper application of *Liu* shows that none of these factors is present here. Contrary to plaintiffs’ claims, there is no evidence that Mr. Shkreli personally profited from the alleged illegal conduct. Plaintiffs argue that such proof consists of the Court’s finding that “Shkreli explains in his direct testimony that he took the actions he did at Vyera based on his belief that the ‘entry of a generic alternative to Daraprim . . . would have a significant effect on my investment in the company.’” Plaintiffs’ Opposition at p. 10 (quoting ECF 865 at p. 133). But at most, this testimony shows Mr. Shkreli’s concern for his investment. It does not constitute proof that he profited from Vyera’s distribution and supply agreements. The record evidence is undisputed that Mr. Shkreli took no salary or other compensation from Vyera, and there is no claim or evidence that he misappropriated any funds from Vyera. Likewise there is no evidence of the value of his shares of stock in Vyera at any point in time (other than the value of his initial investment) or that he ever sold a single share for a profit (or a loss) such that one could show profit in that way. In short, there is no evidence of profit by Mr. Shkreli.

Similarly, there is a lack of record evidence of Mr. Shkreli’s participation in “concerted wrongdoing” with respect to the allegedly anti-competitive agreements. The record is devoid of evidence that he was involved in either the supply or distribution agreements. Plaintiffs erroneously state that Mr. Shkreli participated in the alleged scheme by “drafting emails for Vyera

businesspeople that were sent verbatim to trading partners.” Plaintiffs’ Opposition, at p. 9. But the record evidence shows that Mr. Shkreli drafted only *a single* email that in any way involved those agreements. And even that one email did not show his participation in the allegedly anticompetitive conduct—*i.e.*, obtaining an exclusive supply agreement from RL Fine. Instead, in the email, Mr. Shkreli merely suggested the type and quantity of API that Vyera should order from RL Fine, including products other than pyrimethamine.

Thus, there is a “substantial possibility” that Mr. Shkreli will succeed in challenging the Court’s order imposing joint and several liability against him.

D. Plaintiffs Fail to Rebut that the Court Erred in Holding that Plaintiffs Had Met Their Burden to Prove the Relevant Product Market.

The relevant product market that Plaintiffs defined in the Amended Complaint is “FDA-approved pyrimethamine products.” Am. Compl. at ¶ 292. The Court held that plaintiffs had succeeded in proving that this is the relevant product market in which to assess the competitive effects in this case. As defined, this product market does not depend upon whether the product is used for prophylaxis or the treatment of active disease. But in their Opposition, Plaintiffs point to evidence that supports a different relevant product market, pyrimethamine for “the treatment of active toxoplasmosis.” *See* Plaintiffs’ Opposition, at p. 11 (“FDA-approved pyrimethamine is the ‘only pharmaceutical to receive [the Opportunistic Infections Guideline’s highest possible] rating for the treatment of *active toxoplasma encephalitis*’... Vyera executives acknowledged that TMP-SMX is ‘medically inferior’ for the treatment of *active toxoplasmosis*.”) (emphasis added). Plaintiffs cannot have it both ways-- pleading a product market that is not defined by treatment alternatives and then using evidence of treatment alternatives to support the same product market.

When the record evidence concerning all toxoplasmosis treatments is considered, one cannot escape the conclusion that the relevant market is not limited merely to Daraprim. Indeed,

Plaintiffs' Opposition does not contest that TMP-SMX is the gold standard treatment for toxoplasmosis prophylaxis. However, plaintiffs use this fact to seek to exclude TMP-SMX from the relevant market, claiming that it serves "distinct customers" from FDA-approved pyrimethamine, thereby turning a blind eye to the fact that FDA-approved pyrimethamine can also be used prophylactically. *Id.* The record evidence shows that the relevant product market consists of other products, including one – TMP-SMX – that is preferred to pyrimethamine for toxoplasmosis prophylaxis.

Accordingly, plaintiffs failed to prove their proposed relevant product market and Mr. Shkreli is likely to succeed on the merits of his challenge to the Court's holding on relevant market.⁵

III. CONCLUSION

For all of the foregoing reasons, and for all those set forth in Mr. Shkreli's opening brief, Mr. Shkreli's Motion to Stay Order for Permanent Injunction Pending Appeal should be granted.

Dated: April 11, 2022

Respectfully submitted,

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⁵ Mr. Shkreli rests on the arguments in his opening brief for the reasons why the other relevant factors (irreparable harm, injury to plaintiffs, and the public interest) support a stay of the injunction.

CERTIFICATE OF SERVICE

I certify that on April 11, 2022, a copy of the foregoing was served upon all counsel of record in this matter using the Court's CM/ECF system.

/s/Andrew J. Rudowitz